Supreme Court of the United States

No. 30—October Term, 1948

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LELORD KORDEL,
Petitioner (Appellant),

v.

THE UNITED STATES OF AMERICA.

PETITION OF THE APPELLANT FOR A REHEARING.

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PETITION FOR REHEARING.

Comes now the above-named petitioner, Lelord Kordel, and presents this, his petition for a rehearing of the above-entitled cause, and, in support thereof, respectfully shows:

1.

The allusion, on page 5 of the majority opinion, to "the manner that a committee report of the Congress accompanies a bill"—although, as we shall see, an imperfect analogy—nevertheless has value in demonstrating the Court's interpretation of the language expressd in §201(m) of the Federal Food, Drug, and Cosmetic Act.

The statute [§201(m)] employs the phraseology "*accompanying* such article." A committee report, on the other hand, customarily reads "Report (*To accompany* S. 2800)." The expression *to accompany* implies future action, the *to* relating to *purpose*. See *Webster's New International Dictionary*, 2nd ed., unabridged. Actually, such a report is *intended to accompany* the designated bill. And that, indeed, is precisely what this Court has read into the stat-

utory provision, amending the expression "accompanying such article"—with its connotations of immediacy and concomitance—to "written, printed, or graphic matter * * * *intended to accompany such article.*"

The first objection to such a critical and far-sweeping "amendment" is that it goes far beyond the obvious intention of the Congress in enacting this legislation. It is indeed unthinkable that the Congress intended to say or imply words that this Court is now putting into its mouth, so to speak. In drafting this bill, the Congress employed the term "intended" when it wished to—and omitted it when it did not. The statutory definitions of "food" and "drug," found in §§201(f) and (g), demonstrate that the Congress had such distinctions clearly in mind. Thus, in defining "food" it declared:

> "The term 'food' means (1) articles *used* for food or drink by man or other animals, * * *"

And it has repeatedly been held that the *intention* that a product be used as food is immaterial. *United States* v. *13 Crates of Frozen Eggs,* 208 Fed. 950, aff'd 215 Fed. 584; *Totten* v. *Pittsburgh Melting Co.,* 232 Fed. 694; *United States* v. *52 Drums Maple Syrup,* 110 F. 2d 914.

On the other hand, its definition of the term "drug" uses the language:

> "* * * (2) articles *intended for use* in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *"

It is a reasonable assumption, therefore, that if the Congress intended to mean that "labeling" include printed matter "intended to accompany such article," it would have said so clearly. Its failure to do so certainly implies that it rejected such a concept.

This Court, incidentally, refused to read the need of intent into the criminal provisions of the Act in the *Dotterweich* case [320 U. S. 277], basing its conclusion on Congressional intention. Its disregard for all niceties of legal construction in the instant case to interpret "accompanying" to signify "intended to accompany" is, therefore, all the more illogical.

Moreover, should the Court maintain its privilege of literally re-writing this provision, its conclusion cannot, in justice, be applied to the facts of the case at bar. No evidence was introduced at the trial that the petitioner "intended" that the printed matter "accompany" the products, nor is such a suggestion capable of being implied (R. 161, 167, 132, 133, 145, 146, 149, 335). On the contrary, the mere fact in one instance that the circular was mailed to a dealer (*not* the consumer) eighteen months *after* the product was shipped mitigates against any assumption of this nature. The goods undoubtedly had been sold and consumed many, many months before literature—allegedly describing *its* "uses"—was forwarded. Were it petitioner's intention that the two "accompany" each other, it is wholly unreasonable that he wait from 1942 to 1944 to send along "directions."

2.

That the import of the majority decision places every manufacturer and distributor of food, drugs, devices, and cosmetics in intolerable jeopardy is undeniable. For in its most elementary terms it means that such businessmen are confronted with the possibility that should *any* piece of advertising matter—going to dealers or to the consumer—be considered "false or misleading," then they may be

criminally charged with *every shipment* of the product made to such consignee, limited only by the statute of limitations. For example, if shipments of goods had been made weekly to a retailer and the manufacturer is thereafter unlucky enough to send a "misleading" circular to the dealer, he is open to prosecution for up to *one hundred and fifty shipments!*[1]

To dismiss this argument as excessive exaggeration overlooks the fact that, in substance, that is precisely what has occurred in this case. Surely, under this state of affairs the views of the dissenting justices should prevail *and the Government be put to affirmative proof in a criminal case to establish that the defendant intended that the circular accompany a specific food or drug to a specific consumer or group of consumers.* Only in such safeguards can the constitutional rights of our citizenry be protected.

This Court should give solemn reconsideration to judicial "legislation" that carries such wide-flung and serious implications and results.

3.

The majority opinion declares (p. 2):

> "Section 301(a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded. It is misbranded according to §502(a) if its 'labeling' is false or misleading in any particular, *unless the labeling bears 'adequate directions for use.'*"

The italicized words disclose a lamentable misunderstanding, not only of the charges brought against the peti-

[1] The "misleading" circular may have been prepared innocently and without intent to violate the law. *United States* v. *Dotterweich*, 320 U. S. 277.

tioner—which were based on "false or misleading" labeling [§502(a)] and *not* inadequate "directions for use" [§502(f)(1)]—but of the structure and substance of the Federal Food, Drug, and Cosmetic Act. The erroneous and misleading character of this statement is certain to invalidate acceptance of any conclusions arrived at through such cloudy and inaccurate knowledge of the statute itself.

Actually, the "false or misleading" section and the "direction for use" provision rest on two entirely different concepts and approaches to enforcement. The first is a negative prohibition, the second is an affirmative labeling requirement. The first is judged in terms of consumer deception, the second, however, only in terms of *adequacy* or *omission*.[2] Labeling, consequently, is *not*—as the decision has it—"false or misleading in any particular, unless the labeling bears adequate 'directions for use.'" The two have absolutely no relevancy to each other.

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[2] For example, §2.106(a), Title 21, Code of Federal Regulations, reads:

§2.106. (a) Directions for use may be inadequate by reason (among other reasons) or omission, in whole or in part, or incorrect specification of—

(1) directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or distributor, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;

(2) quantity of dose (including quantities for persons of different ages and different physical conditions):

(3) frequency of administration or application;

(4) duration of administration or application;

(5) time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);

(6) route or method of administration or application; or

(7) preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

The Court obviously fell into its ambiguity as a result of the Government's efforts to becloud the issues by injecting the "directions for use" concept.[3] But the latter involves an entirely different enforcement procedure, bearing no relation to the charge brought against petitioner of issuing "false or misleading labeling."

As we have observed, the directions for use required by the statute are judged only in the light of their *adequacy*. It is true that §2.106(a)(1) of the General Regulations (see footnote 2) states that such directions may be inadequate because of the omission of directions in all conditions for which the drug is advertised. And it is equally obvious that the Government has the right to enforce this provision where the *advertising matter* mentions a disease condition *about whose use the drug's label is silent*. (See cases cited *infra*.) In such instances, the "directions for use" are *inadequate*—but *not* false or misleading, the charge in the instant case.

What the Government has done here is to attempt to bolster an insupportable allegation of "false or misleading labeling" when it had available an enforceable charge of inadequate directions for use! To do so, it has had to confuse this Court as to the nature of labeling and invoke the concept of false or misleading "directions" or "uses," it has had to force this Court into conjuring up a "new crime," it has had to persuade this Court that an "hiatus" existed —when all the time it possessed—and overlooked in its pleading—an acceptable, established method of proceeding against a drug misbranded because of the inadequacy of its directions for use.

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[3] Incidentally, this concept was only raised on appeal—and appears nowhere in the pleadings nor was it presented for consideration at the trial.

This proper approach is exemplified in *United States* v. *150 Packages, etc. "Bush Mulso Tablets," etc.*, D. C., E. D. Mo., E. D., No. 4415, July 11, 1947, *C. C. H. Food Drug Cosmetic Law Reports*, p. 7607, involving the identical facts here. It similarly is evident in *United States* v. *Colgrove*, D. C., S. D. Calif., C. D., No. 5992-WM Civil, Feb. 14, 1947, *C. C. H., op. cit.*, p. 7581, wherein the court held that where, *through advertising media*, a drug is represented to be a treatment for psoriasis, eczema, leg sores, leg ulcers and athlete's foot, and the labeling on the drug does not bear adequate directions for use in the treatment of these ills, conditions and diseases, the drug is misbranded *in violation of §502(f)(1)* of the Act. Under these authorities, the Government could have proceeded against the petitioner for violation of this section.

It is emphatically submitted that where a remedy is available *without* distortion of an Act of Congress this Court should not write in a new crime to take care of a "hiatus" *that does not exist.*

4.

The majority opinion argues (p. 5) that since §201(m) does not say "accompanying such article *in the package or container*," it sees no reason to read this condition into the text.

But the *only* Congressional comment on the bill's phraseology (Senate Report No. 361, to accompany S. 5, 74th Cong., 1st Sess., p. 4) expressly refers to "* * * side panels of the labeling or *in circulars within the package.*" (Cited Petitioner's Brief, p. 19.) It seems clear that the Court has violated its own injunction by reading into the provision a breadth not contemplated by the Congress.

5.

The majority opinion states in reference to the "literature" (p. 3):

> "Nowhere else was the purchaser advised how to use them [the drugs]."

This conclusion—so essential to the reasoning of the Court—is unfortunately wholly inaccurate. One need only examine the labels of the products to observe how carefully and explicitly the labels give full directions for use. (See Petitioner's Brief, p. 23, for illustration.) But worse than any injustice that may be shown the petitioner is the doubt this statement throws on another provision of the Act, and a prior decision of this Court.

With several exceptions, the products involved in this case are vitamins and minerals—so-called "special dietary foods." §403(j) of the Act states:

> "SEC. 403. A food shall be deemed to be misbranded—
>
> • • • • • •
>
> (j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses."

Pursuant to this provision, the Federal Security Administration has issued comprehensive regulations relating to dietary food labeling (Code of Federal Regulations, Title 21, Chap. 1, §§125.1-125.8). Both in his Findings of Fact (6 Federal Register 5921) and in these regulations the

Administrator carefully surveyed what information is necessary *in order to inform the purchaser of the value and uses of such products.* This Court, moreover, in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218, has had occasion to support the Administrator's findings in connection with a similar provision of the Act.

Petitioner in the instant case labeled each vitamin and mineral product in full accordance with such informative regulations. Nor has the Government attacked either the sufficiency of that information or its accuracy. How can it categorically be stated, therefore, that "nowhere else was the purchaser advised how to use" these products, save in the "literature"? While such a statement may be appropriate in the *Urbeteit* case, surely it is not in the case at bar. Yet if it be acknowledged that the *labels* contained all information "necessary in order fully to inform purchasers as to its value for such uses" the whole logic of the Court's decision fails.

This Court need not be told that decisions cannot be written in a vacuum of unsupported suppositions, nor should guilt be glibly imposed on this petitioner where the facts proclaim otherwise.

6.

A decision such as this which so disturbs the delicate balance of an intricate Federal statute cannot but serve to confuse and dismay those whose duty it is to interpret and apply its provisions. This feeling extends not only to industry lawyers but also to all firms engaged in the marketing of foods, drugs, and cosmetics (cf. *The New York Times*, Nov. 24, 1948).

As it stands, the decision of a divided court goes far beyond what the administrative agency itself sought in the

original draft of the Food, Drug, and Cosmetic Act (cf. S. 1944, 73rd Cong., 2nd Sess., *e. g.*, no seizure for false advertisements) and what the Congress was willing to allow under any circumstances (cf. Wheeler-Lea Amendment of 1938). By force of this decision, all food, drug, and cosmetic advertising—provided it mentions any condition of use—is considered "labeling" and subject to the injunction that it not be "false or misleading in *any* particular." The Federal Trade Commission Act, §15, on the other hand, defines "false advertisement" as:

> "* * * an advertisement, other than labeling, which is misleading in a *material* respect; * * *".

And goes on to state:

> "No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of the formula showing quantitatively each ingredient of such drug."

Similarly, the postal laws require of drug advertising that the means employed be proved *fraudulent* (Criminal Code, §215). These commercial safeguards, so necessary in the case of drug advertising, are not available under the Food, Drug, and Cosmetic Act.

Where such a material change has been made in a law of such universal application, the minority opinion here should at least prevail so that defendants be placed on notice of the precise violation charged in the information, and, more important, so that the Government has the burden of demonstrating affirmatively the interrelation and inter-reliance of the literature and the goods. As demonstrated in the instant case, this is *not* an essential part of the proof.

7.

The Court has dismissed petitioner's argument that he was wrongfully prosecuted by information and not by indictment by citing *Duke* v. *United States*, 301 U. S. 492, and §7(a) of the Rules of Criminal Procedure. Neither is applicable nor controlling. §7(a) was not effective at the time the informations were filed herein. The *Duke* case distinguishes only between petty offenses and misdemeanors and does not treat of the major problem herein involved. An important constitutional safeguard has, it is believed, been brushed aside without sufficient consideration.

For the foregoing reasons it is respectfully urged that this petition for a rehearing be granted and that the judgment of the circuit court of appeals be, upon further consideration, reversed.

Respectfully submitted,

ARTHUR D. HERRICK,
Counsel for Petitioner.

CERTIFICATE OF COUNSEL

I, ARTHUR D. HERRICK, counsel for the above-named LELORD KORDEL, do hereby certify that the foregoing petition for a rehearing of this cause is presented in good faith and not for delay.

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Counsel for Petitioner.